

Atty Dkt No. 8500-0262  
Serial No. 09/0 01,577

### REMARKS

All originally filed claims, i.e., claims 1-81, have been examined and addressed in the Office Action under reply, as the requirements for restriction and election of species have now been withdrawn. In the Office Action, the claims were addressed as follows:

- (1) Claims 1-62 and 78-80 stand allowed;
- (2) Claim 63 stands objected to as improperly dependent, and claims 67-69 stand objected to as depending from an objected to base claim; and
- (3) Claims 64-66, 70-77, and 81 stand rejected under 35 U.S.C. §112 ¶2 as indefinite.

With this amendment, claim 72 has been canceled and claims 25, 29, 40, 42, 47, 63, 64, 71, 73, 74, and 81 have been amended. Accordingly, claims 1-71 and 73-81 are now pending.

#### The amendments to the specification:

The amendments to the specification correct minor and inadvertent errors in the application as filed. No substantive changes have been made, and no new matter has been added.

#### The amendments to the claims:

The amendments to claims 25, 29, 40, 42, and 47 are for the sole purpose of correcting minor and inadvertent errors primarily of a typographical nature.

Claim 63 has amended to correct the error in dependency noted by the Examiner. The claim now correctly depends from claim 62.

Claim 64 has been amended to recite that the therapeutically effective amount of the active agent is actually an amount effective to provide a desired pharmacological effect on the central nervous system (CNS) of a mammalian individual to whom the formulation is administered.

Claim 70 has been amended in a similar manner, with claim 70 now reciting that the ionizable compound is present in an amount that, when the compound is ionized, results in a therapeutically effective amount of the pharmacologically active cation, wherein the "therapeutically effective amount" of the cation is recited as in claim 64. Claim 81 has been amended along the same lines.

Claims 64, 73, and 74 have been amended to reflect the aforementioned changes in the base claims as well as the cancellation of claim 72.

The aforementioned amendments are fully supported by the original disclosure, including the originally filed claims. See, for example, page 7, lines 3-17 (CNS active agents), page 11, lines 4-6 ("effective amount"), pages 15-16, bridging paragraph (CNS active agents), and claim 81 (the "therapeutically effective amount" is to provide a pharmacologic effect in the CNS).

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The 35 U.S.C. §112 ¶2 rejection:

Claims 64-66, 70-77, and 81 stand rejected as indefinite on the ground that the term "effective amount" was not explicitly associated with a recited function. It is understood that "definiteness" under 35 U.S.C. §112 ¶2 merely requires that "one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Miles Laboratories v. Shandon, Inc.*, 27 U.S.P.Q. 2d 1123, 1126 (1993). Here, there is ample explanation throughout the specification regarding pharmacologically active agents, "effective amounts" thereof, and indications for which the agents are useful. See applicants' definition of the term "effective amount" on page 11, lines 4-6, which is in accordance with the generally understood meaning of the term: that is, an "effective amount" of an active agent is a "nontoxic but sufficient amount of the agent to provide the desired effect." Elsewhere in the specification, various active agents and indications are set forth; see Section IIIA of the Detailed Description, beginning on page 15.

While not wishing to acquiesce in the rejection, however, and for the sole purpose of expediting prosecution, applicants have amended claims 64, 70, and 81 as explained above to specify that the therapeutically effective amount of the active agent is an amount that will provide a desired pharmacological effect in the CNS of a mammalian individual to whom the formulation is administered. Support for the added terminology is set forth in the preceding section.

Accordingly, applicants respectfully request withdrawal of the 35 U.S.C. §112 ¶2 rejection in light of the foregoing.

The Objections:

The objection to claim 63 as depending from an incorrect claim has been addressed by amendment of that claim, as explained above. The objection to claims 67-69 as depending from an objected-to base claim is now moot. Applicants accordingly respectfully request withdrawal of the aforementioned objections to the claims.

All outstanding issues having been addressed herein, applicants submit that the application is now in condition for allowance. A notice to that effect is respectfully solicited.

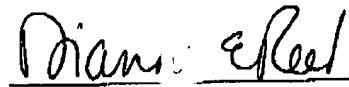
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If the Examiner has any questions regarding this Amendment or the application in general, he is welcome to contact the undersigned by phone at 650-330-0350 or by e-mail at [dianne@reedpatent.com](mailto:dianne@reedpatent.com).

Respectfully submitted,

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